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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/070,764	03/12/2002	John Andrew Chaddock	1581.0900000/RWE/MTT	2729

26111 7590 06/19/2006

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EXAMINER

DEVI, SARVAMANGALA J N

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 06/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/070,764

Applicant(s)

CHADDUCK ET AL.

Examiner

S. Devi, Ph.D.

Art Unit

1645

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 May 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 41-47 ~~is/are~~ are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 41-47 ~~is/are~~ are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

RESPONSE TO APPLICANTS' AMENDMENT

Applicants' Amendment

- 1) Acknowledgment is made of Applicants' amendment filed 05/23/06 in response to the non-final Office Action mailed 02/23/06.

Status of Claims

- 2) Claim 41 has been amended via the amendment filed 05/23/06.
New claims 46 and 47 have been added via the amendment filed 05/23/06.
Claims 41-47 are pending and are under examination.

Prior Citation of Title 35 Sections

- 3) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

Prior Citation of References

- 4) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

Rejection(s) Withdrawn

- 5) The rejection of claim 41 made in paragraph 17(a) of the Office Action mailed 02/23/06 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.
- 6) The rejection of claim 41 made in paragraph 17(b) of the Office Action mailed 02/23/06 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.
- 7) The rejection of claims 42-45 made in paragraph 17(c) of the Office Action mailed 02/23/06 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the base claim.

New Rejection(s) Based on Applicants' Amendment

The new rejection(s) set forth below are necessitated by Applicants' amendments and/or submission of new claims.

Rejection(s) under 35 U.S.C. § 112, First Paragraph (New Matter)

8) Claims 41-47 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 41 as amended, and the new claims 46 and 47, include the limitations: ‘wherein said second ligand binds to the *and/or* to the *clostridial toxin part* of the first ligand-clostridial toxin complex’ [Emphasis added]. Applicants point to lines 4-17 and 27-32 on page 6 of the specification and state that the amended claim 41 and new claim 46 have support therein. Applicants state that support for new claim 47 can be found at lines 18-22 of page 3 and lines 6-23 of page 8 of the specification. However, there appears to be no descriptive support in these parts of the specification for the method now claimed. First, a second ligand that selectively binds to the first ligand part of the first ligand-clostridial toxin complex **and** to the clostridial toxin part of the first ligand-clostridial toxin complex has no descriptive support in the specification, as originally filed. Secondly, a method which includes the second step wherein a second ligand binds to the ‘clostridial toxin part of the first ligand-clostridial toxin complex’, has no descriptive support in the specification, as originally filed. A review of the specification indicates the following. Lines 4-6 on page 10 of the specification describe that a further ligand binds selectively to the first ligand, or binds selectively to a complex of the first ligand with toxin. Lines 11-13 of page 10 of the specification describe that the second ligand can be a further antibody or immunoglobulin binding domain which binds to the first antibody or to a complex of the first antibody with toxin. Line 17 of page 10 describes the use of the second ligand to remove antibody-toxin complexes. Therefore, the above-identified limitations in the claims are considered to be new matter. *In re Rasmussen*, 650 F2d 1212 (CCPA, 1981). New matter includes not only the addition of wholly unsupported subject matter but also, adding specific percentages or compounds after a broader original disclosure, or even omission of a step from a method. See M.P.E.P 608.04 to 608.04(c).

Applicants are respectfully requested to point to specific pages and lines providing the descriptive support in the specification as originally filed, for the new limitations, or remove the new matter from the claim(s).

Rejection(s) under 35 U.S.C. § 112, Second Paragraph

9) Claims 41-47 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite, for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

(a) Claim 41 is vague and indefinite in the limitation: 'fragments or conjugates', because it is unclear what is encompassed in this limitation. What constitutes 'fragments' or 'conjugates', and how much of the original clostridial toxin's structure must be retained such that the resultant product qualifies as a 'fragment' is not clear. Does a single amino acid or a dipeptide of the clostridial toxin qualify as a 'fragment'? What are conjugates composed of, i.e., what are the fragments conjugated to, is unclear. The metes and bounds of the structure encompassed in the limitation 'fragments or conjugates' are indeterminate.

(b) Claim 41 lacks proper antecedent basis in the limitation 'conjugates thereof' in lines 7, 9, 20 and 22 of the claim. For proper antecedent basis, it is suggested that Applicants replace the limitation with --the conjugates thereof--.

(c) Claim 41 lacks proper antecedent basis in the limitation 'clostridial toxin fragments or conjugates thereof' (see last two lines). For proper antecedent basis, it is suggested that Applicants replace the limitation with the limitation --the clostridial toxin fragments or the conjugates thereof--.

(d) Claim 41 is further vague, indefinite and confusing in the limitations: 'wherein said second ligand binds to the first ligand-clostridial toxin complex wherein said second ligand binds to the first ligand part of the first ligand-clostridial toxin complex and/or to the clostridial toxin part of the first ligand-clostridial toxin complex' (see part ii), because it is unclear how the same 'said second ligand' can bind to (a) the first ligand-clostridial toxin complex; (b) the first ligand part of the first ligand-clostridial toxin complex; and (c) the clostridial toxin part of the first ligand-clostridial toxin complex. Is this one single second ligand that has binding specificity for all these components?

(e) Analogous rejection and criticism applies to new claims 46 and 47.

(f) Claim 46 is vague and indefinite in the limitation: 'fragments', because it is unclear what is encompassed in this limitation. What constitutes 'fragments', and how much of the original clostridial toxin's structure must be retained such that the resultant product qualifies as a 'fragment'

is not clear. Does a single amino acid or a dipeptide of the clostridial toxin qualify as a 'fragment'? The metes and bounds of the structure encompassed in the limitation 'fragments' are indeterminate.

(g) Claim 46 lacks proper antecedent basis in the limitation 'clostridial toxin fragments' (see last line). For proper antecedent basis, it is suggested that Applicants replace the limitation with the limitation --the clostridial toxin fragments--.

(h) Claim 47 lacks proper antecedent basis in the limitation 'clostridial LH_N' (see last line). For proper antecedent basis, it is suggested that Applicants replace the limitation with the limitation --the clostridial LH_N--.

(i) Claims 42-45, which depend from claim 41, are also rejected as being indefinite because of the indefiniteness identified above in the base claim.

Remarks

10) Claims 41-47 stand rejected.

11) Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. Applicants are reminded of the extension of time policy as set forth in 37 C.F.R 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

12) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Central Fax number (571) 273-8300, which receives facsimile transmissions 24 hours a day and 7 days a week.

13) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the

Serial No. 10/070,764
Art Unit: 1645

PAIR system, see <http://pair-direct.uspto.Mov>. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

14) Any inquiry concerning this communication or earlier communication(s) from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail service. The Examiner can normally be reached on Monday to Friday from 7.15 a.m to 4.15 p.m. except one day each bi-week which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

June, 2006


S. DEVI, PH.D.
PRIMARY EXAMINER